**IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE**

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| BOEHRINGER INGELHEIM INTERNATIONAL GmbH and BOEHRINGER INGELHEIM PHARMACEUTICAL, INC.,<br><br>Plaintiffs and Counterclaim Defendants,<br><br>v.<br><br>MYLAN PHARMACEUTICALS INC.,<br><br>Defendant and Counterclaim Plaintiff. | Civil Action No.: 05-0854 (KAJ) |

**REPLY BRIEF IN SUPPORT OF MYLAN PHARMACEUTICALS INC.'S MOTION TO STRIKE PLAINTIFFS' ALLEGATIONS CONCERNING WILLFUL INFRINGEMENT AND TO BAR ALL DISCOVERY RELATING THERETO**

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## INTRODUCTION

Boehringer's opposition brief fails to come to grips with what is now controlling Federal Circuit law: a plaintiff cannot base a willfulness claim on the mere filing of an ANDA application or certification. *See Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004). While Boehringer maintains that *Glaxo* is not binding here because no paragraph IV certification was filed in that case, the Federal Circuit crafted its holding to expressly *include* such certifications. *See id*. at 1350 ("we now hold that the mere fact that a company has filed an ANDA application *or certification* cannot support a finding of willful infringement") (emphasis added). Although Boehringer relies on *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000), for the proposition that the filing of a baseless paragraph IV certification justifies a finding of willfulness for purposes of awarding attorney's fees, the Federal Circuit in *Glaxo* made clear that *Yamanouchi* means no such thing. *See Glaxo*, 376 F.3d at 1350 (explaining that "in *Yamanouchi*, we did not agree that the generic company had engaged in willful infringement," despite finding in that case that "the generic company failed to present even a *prima facie* case of invalidity in filing its paragraph IV certification").

Finally, Boehringer attempts to overcome *Glaxo* by arguing that Boehringer's mere allegation of willfulness is sufficient to invoke invasive discovery of otherwise privileged information concerning Mylan's decision to file a paragraph IV certification – specifically what *Glaxo* prohibits. If Boehringer happens to prevail in the litigation then the sufficiency of Mylan's 29-page, single-spaced, statutorily-mandated notification letter can then be assessed.

Because there remains no issue of material fact, Mylan is entitled to a judgment dismissing Boehringer's claim of willfulness and all discovery directed thereto.

## ARGUMENT

### I. The Federal Circuit's Holdings In *Yamanouchi* And *Glaxo* Addressed Paragraph IV ANDA Certifications.

Despite the direct applicability of the Federal Circuit's language in *Glaxo*, Boehringer asserts that the case need not be followed because no paragraph IV certification had been filed by the generic manufacturer. Boehringer at 2-3. While the defendant in *Glaxo* may not have filed such a certification, the defendant in *Yamanouchi* did – and the Federal Circuit found that the filing of a certification in that case did not support a finding of willful infringement. *See Glaxo*, 376 F.3d at 1350 (noting that in *Yamanouchi*, "the generic company failed to present even a *prima facie* case of invalidity in filing its paragraph IV certification," but that even so "we did not agree that the generic company had engaged in willful infringement . . ."). The court's discussion in *Yamanouchi* – as clarified by the court in *Glaxo* – clearly applies to the filing of paragraph IV certifications.

Despite this, Boehringer flatly asserts, without evidence or argument, that the court's holding in *Glaxo* – that the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4) – is inapplicable "[b]ecause there was no paragraph IV certification" in *Glaxo*. Boehringer at 3. The paragraph preceding the quoted language from *Glaxo*, however, expressly refers to such certifications:

> In *Yamanouchi* . . . , this Court determined that a baseless and "wholly unjustified" *paragraph IV certification* in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding. In *Yamanouchi*, the district court had found that the generic company's ANDA filing constituted willful infringement, but we did not adopt that rationale on appeal. Instead we cautioned that the trial court "need not have elevated the ANDA certification into a finding of willful infringement" and held that Danbury's entire conduct justified the award of attorney's fees, noting that the generic company failed to present even a prima facie case of invalidity in filing its *paragraph IV certification*, hence making a baseless filing, and proceeded to present its case in litigation despite

> "glaring weaknesses." Therefore, in *Yamanouchi*, we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification. Such unjustified litigation and misconduct has always justified a finding of an exceptional case.
>
> Consequently, as suggested by *Yamanouchi*, we now hold that the mere fact that a company has filed an ANDA application *or certification* cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4).

376 F.3d at 1350-51. (citations omitted; emphasis added). Every mention of a "certification" in the above paragraphs refers to a *paragraph IV certification*. Indeed, Boehringer offers no other logical antecedent to which the Federal Circuit could have been referring. The filing of an ANDA certification – whether meritorious or baseless – simply cannot justify a finding of willful infringement under the law of the Federal Circuit.

## II. Boehringer's Reading Of *Yamanouchi* Ignores The Federal Circuit's Treatment Of That Decision In *Glaxo*.

Boehringer's suggestion that a finding of willful infringement is the same thing as a finding that a paragraph IV certification is "baseless," Boehringer at 3, is precisely the misreading of *Yamanouchi* that the Federal Circuit dispelled in *Glaxo*. Boehringer maintains that in *Yamanouchi*, defendant's "bad faith submission of its Paragraph IV certification formed part of the basis for the holding that the case was exceptional" and that "the Federal Circuit relied on the same evidence." Boehringer at 4. Boehringer fails to acknowledge, however, that the Federal Circuit expressly disagreed with that reading of *Yamanouchi*. *Glaxo*, 376 F.3d at 1350 ("In *Yamanouchi*, the district court had found that the generic company's ANDA filing constituted willful infringement, *but we did not adopt that rationale on appeal*.") (emphasis added); *see also id.* ("[I]n *Yamanouchi*, *we did not agree that the generic company had engaged in willful infringement* . . . .") (emphasis added). Boehringer's argument also fails to account for

the fact that the Federal Circuit in *Yamanouchi* found willful infringement based on the generic company's repeated and continuous pattern of bad faith. *Glaxo*, 376 F.3d at 1350. As noted in Part I of this Brief, *Yamanouchi* (as clarified by *Glaxo*) stands for the proposition that the filing of an ANDA certification – whether meritorious or baseless – cannot support a willfulness claim.

## III. Boehringer's Argument Illogically Presumes That If Attorneys' Fees Are Sought Then It Has A Right To Willfulness Discovery.

Boehringer's claim to discovery as of right to the reasons underlying Mylan's Paragraph IV certification (other than those set forth in Mylan's 29-page, single-spaced notification letter) is exactly the type of invasive discovery prohibited by the Federal Circuit. Boehringer's nightmarish depiction of a frenzy of baseless-ANDA-filers filing "shot in the dark" Paragraph IV certifications ignores the unique Hatch-Waxman statutory scheme that allows Boehringer to sue Mylan for infringement before Mylan even has tentative approval of its ANDA, much less approval to market commercially. In fact, the Federal Circuit recognized the deterrent effect of its decision when it warned in *Glaxo* that "unjustified litigation and misconduct has always justified a finding of an exceptional case." 376 F.3d at 1350. Thus, the courts will still have a mechanism by which they can deter frivolous filings. But, while a court may consider the objective basis for a paragraph IV certification as one factor in determining whether a finding of an *exceptional case* is justified, that is a separate question from whether such a certification can support a finding of willful infringement, with the attendant resort to opinion letters and intrusive inquiry into the defendant's state of mind. *See* Bloodworth Decl. in support of Mylan's Motion to Strike, Ex. D, 10:12-16 ("I'm amazed at what is almost a prurient interest which patent counsel have in looking at the opinions of each other… the Court nevertheless does not have to encourage it.") (J. Chesler).

Certainly there is no evidence that the drafters of the Hatch-Waxman amendments intended the "highly artificial" act of infringement and its consequential detailed legal and factual basis underlying the filing of the Paragraph IV certification to function as a *de facto* waiver of the work product doctrine and attorney-client privilege protections. Moreover, Boehringer's argument ignores the word "prevailing" in 35 U.S.C. § 285. *See Reply Brief in Support of Barr Laboratories, Inc.'s Motion to Strike Plaintiff's Allegations Concerning Willful Infringement* (D.I. 15), Case No. 05-CV-0700 (D. Del. ) (Nov. 21, 2005) at 7-9. Boehringer collapses the "highly artificial" act of infringement with attorneys' fees under the "exceptional case" doctrine and labels the result "willfulness." But, the Federal Circuit has spoken, and has said that Boehringer's argument must fail.

Because there remains no issue of material fact with respect to willful infringement, dismissal is warranted.

**CONCLUSION**

For the reasons set forth herein, Mylan respectfully requests that this Court grant its Motion to Strike Plaintiffs' Allegations Concerning Willful Infringement And To Bar All Discovery Relating Thereto and issue an Order dismissing Boehringer's claim of willfulness and all discovery directed thereto.

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Dated: January 26, 2006

**CERTIFICATE OF SERVICE**

I hereby certify that on the 26th day of January, 2006, I electronically filed the foregoing document, **REPLY BRIEF IN SUPPORT OF MYLAN PHARMACEUTICALS INC.'S MOTION TO STRIKE PLAINTIFFS' ALLEGATIONS CONCERNING WILLFUL INFRINGEMENT AND TO BAR ALL DISCOVERY RELATING THERETO**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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